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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,341	10/13/2000	Hisakazu Kurita	K0448/7003	5123

7590

09/26/2002

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,341

Applicant(s)

KURITA ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment B, filed 7/12/2002.

Claims 1-12 are in the prosecution.

Response to Arguments

1. Applicant's arguments filed 7/12/2002 have been fully considered but they are not persuasive.

The standing rejection:

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,740,374 ('374) and US 5,866,157 ('157), each by itself or in combination with US 5,271,946 ('946).

US '374 teaches an adhesive composition comprising alkaline salt of the drug (basic salt) and organic acid such as acetic acid. The amount of the drug salt is from 1 to 40 % and the amount of the organic acid is from 10 to 50 % (abstract; col.3, lines 67-68; col.4, lines 1-4, 57, 62; col.9, lines 12-15).

US '157 teaches an adhesive composition comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples).

However, US '374 and US '157 do not disclose the organic acid in the powder from or the mean diameter of the powder particles.

No criticality of the claimed mean diameter of the organic acid powder that provides superior and unexpected results.

The organic acids and their salts are well known in the art to be used in the powder form and they are used in the pharmaceutical composition for oral and topical compositions.

US '946 teaches sodium acetate having a particle size of about 0.1 to 200 micrometer and are used in pharmaceutical compositions such as oral and topical composition in an amount of 5-70 % (col.3, lines 10-33; col.4, lines 38-41; col.6, lines 58-62).

It is an art recognized fact that in order of the particles to penetrate the skin or the mucosa they need to dissolve, and one of ordinary skill in the art would realize that the smaller particles are dissolved faster and absorbed faster through the skin or the mucosa.

Applicants' arguments:

- The main gist of applicants' argument to the above rejection is that none of the cited prior art teaches that the organic acid salt in the form of powder or the specific mean diameter that improves the skin permeability of the drug.
- No motivation to combine the teachings of US '374 or US '157 with US '946.

Examiner's position:

- Both of US '374 and US '157 disclose the combination of base drug and organic acid salt in an adhesive preparation, as claimed by the applicants. The references are silent regarding the state of sodium acetate, and that does not exclude its presence as a powder. Sodium acetate is known as powder; see the "Condensed Medical Dictionary", page 1007, 1008. Applicants failed to show superior and unexpected results that show criticality in the claimed particle sizes. Both references teach that the presence of sodium acetate in the preparation for the same purpose desired by applicants, that is improved percutaneous absorption, see US '374, col.4, lines 47-50, and US '157, col.2, lines 32-39. It is within the skill in the art to determine the diameter of the particle in order to achieve a beneficial effect.

- US '946 is relied upon for the solely teaching of the size of the sodium acetate particles and its use in pharmaceutical compositions. Thus, it would have been obvious to one having ordinary skill in the art to provide a composition comprising a base drug and an organic acid salt in the form of a powder and select the particle size of the powder that required to achieve the desired rate of permeation across the skin.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048.

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The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
